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(54) **CUSTOM LINKABLE IMAGING AND MULTIFUNCTIONAL TRAY**

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(51) **Int. Cl.**

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A61B 5/055	(2006.01)
A61B 5/00	(2006.01)
A61B 6/14	(2006.01)
A61B 6/00	(2006.01)

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CPC ***A61C 1/084*** (2013.01); *A61B 5/055* (2013.01); *A61B 5/4547* (2013.01); *A61B 6/14* (2013.01); *A61B 6/583* (2013.01); *A61C 9/004* (2013.01)

(58) **Field of Classification Search**
CPC A61C 9/0006
USPC 433/37, 50, 75, 76, 72, 68, 214; 378/38–40
See application file for complete search history.

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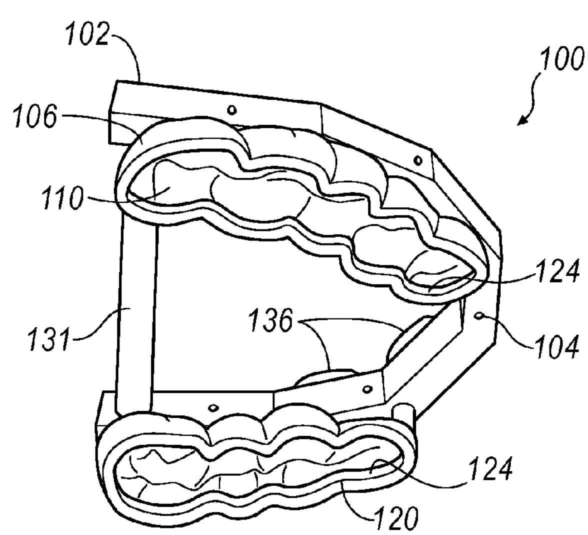
(57) **ABSTRACT**

A multifunctional diagnostic tray configured to clasp an oral structure when positioned in a mouth. The tray may be digitally designed from surface scan data of the mouth and manufactured. The tray provides a temporary positioning reference location that may be viewed in a tomography scan data set. The tray may be used to orient and verify the tomography scan data set and the surface scan data set to create a combined master data file that may be used to determine the appropriate location for a dental implant or other dental procedure.

23 Claims, 6 Drawing Sheets



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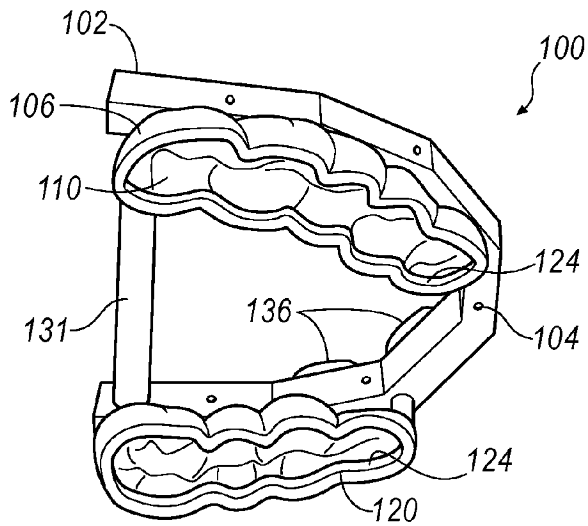

FIG. 1

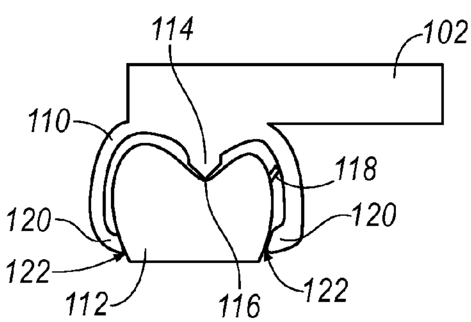

FIG. 2A

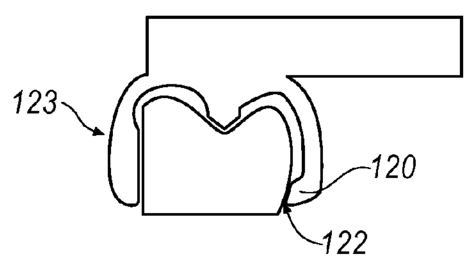

FIG. 2B

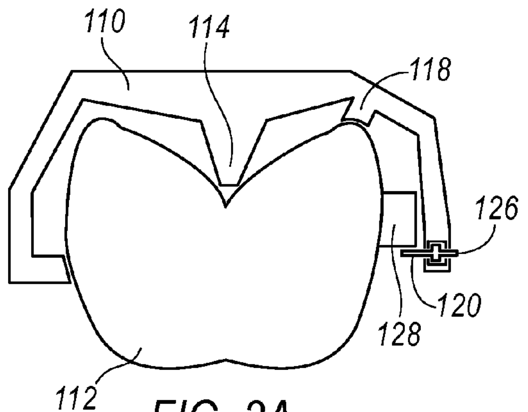

FIG. 3A

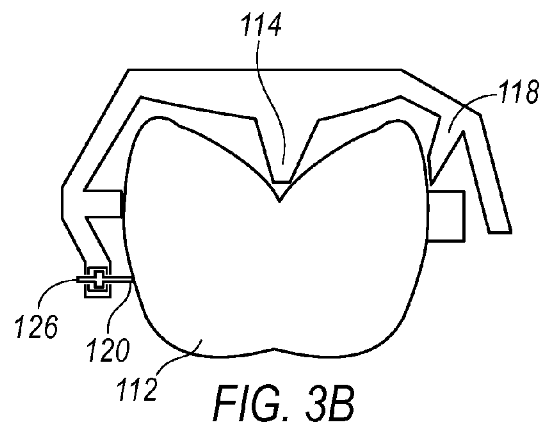

FIG. 3B

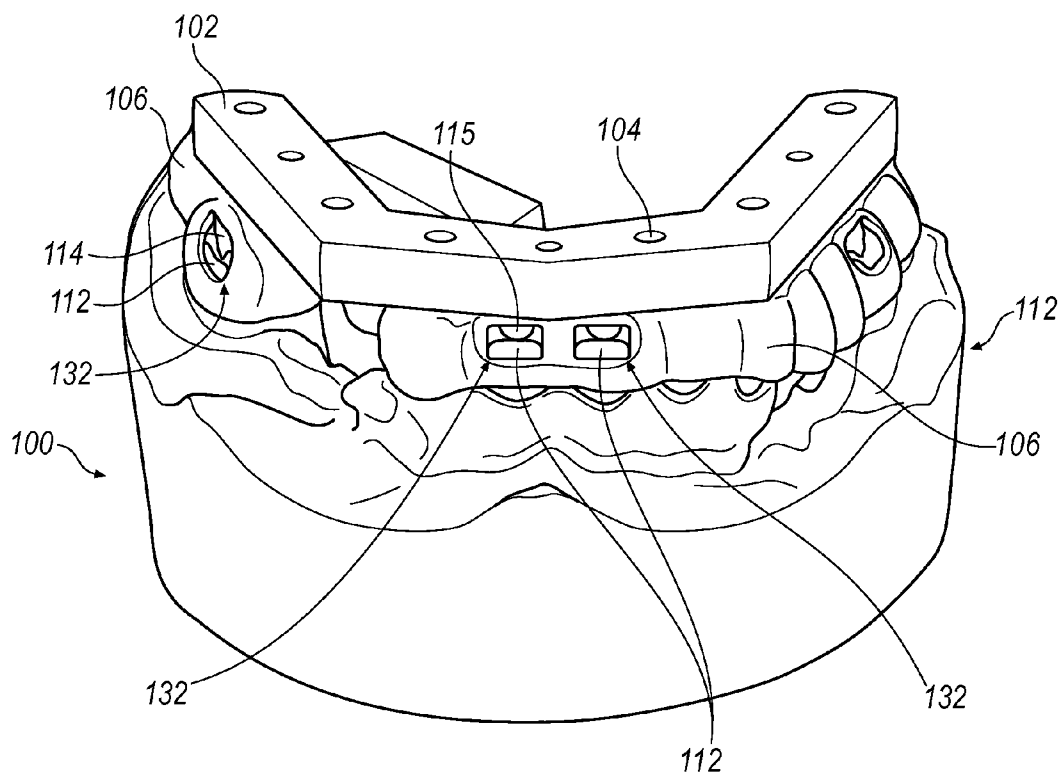

FIG. 4

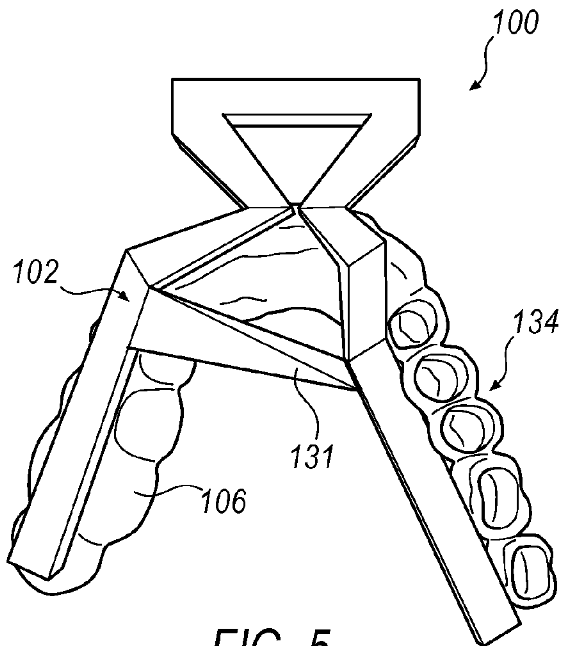

FIG. 5

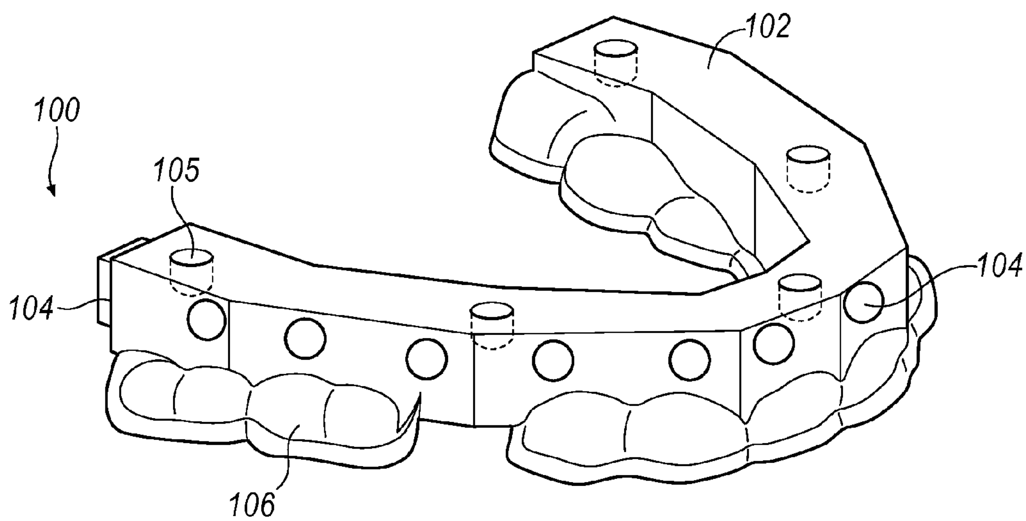

FIG. 6

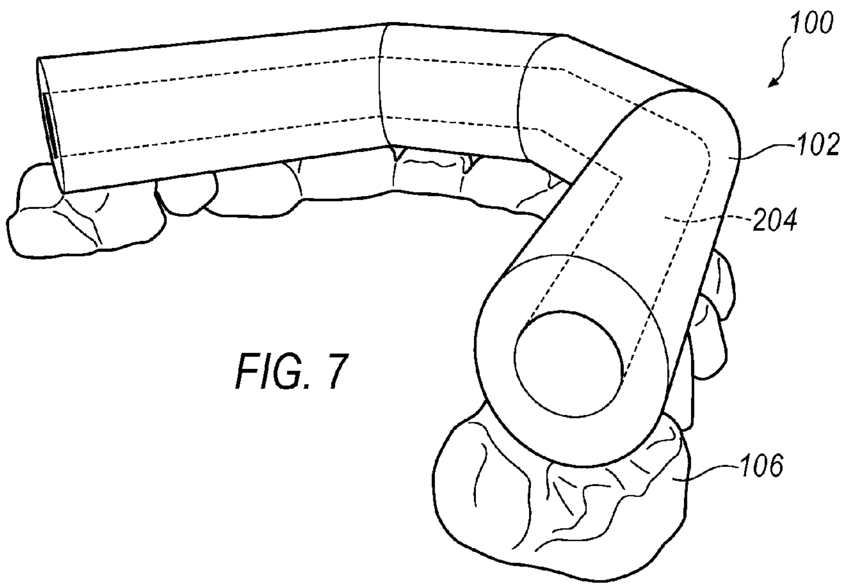

FIG. 7

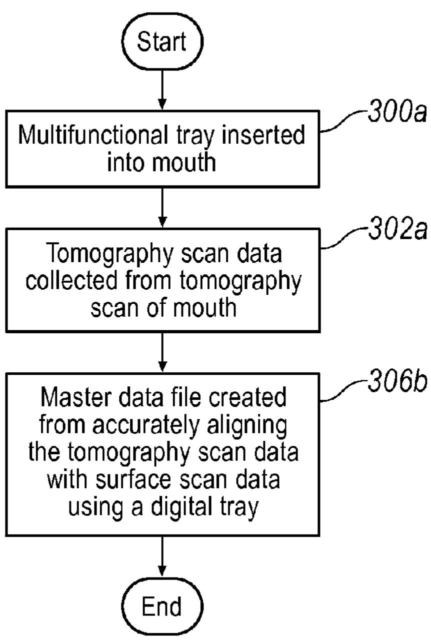

FIG. 8A

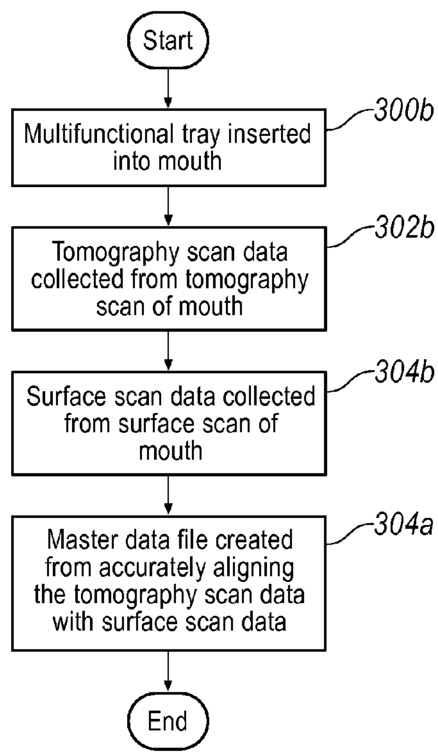

FIG. 8B

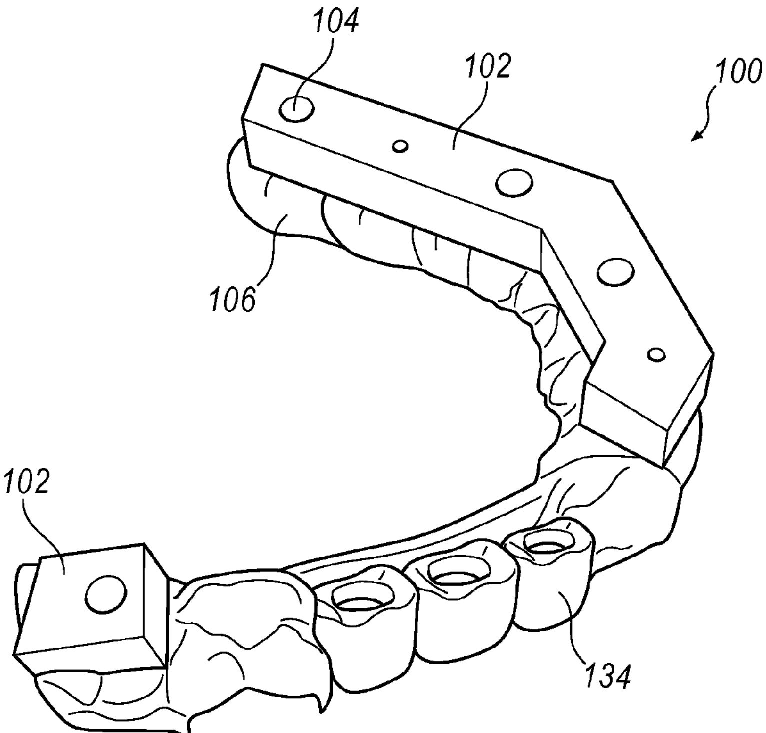

FIG. 9

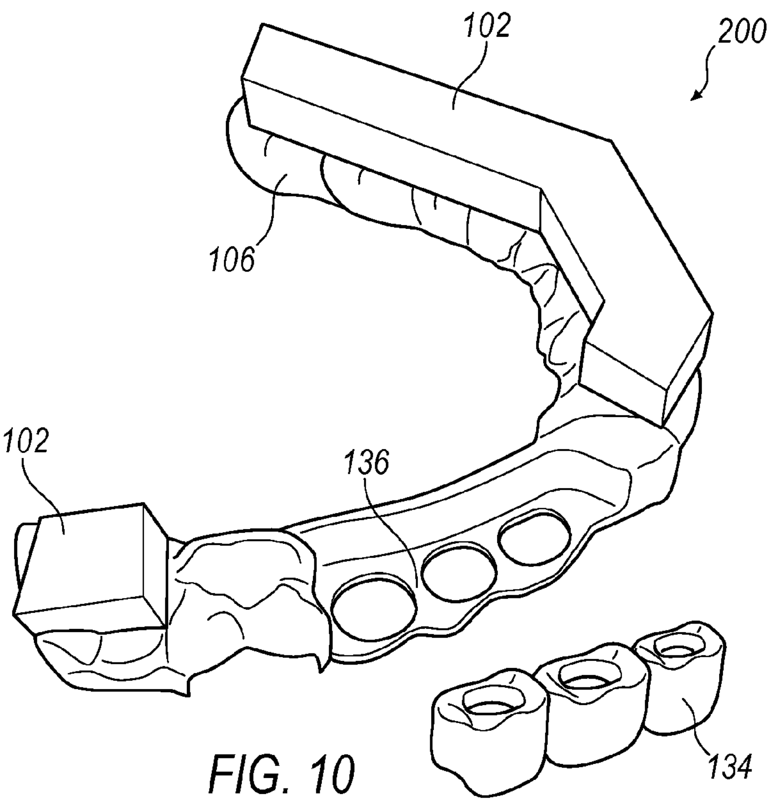

FIG. 10

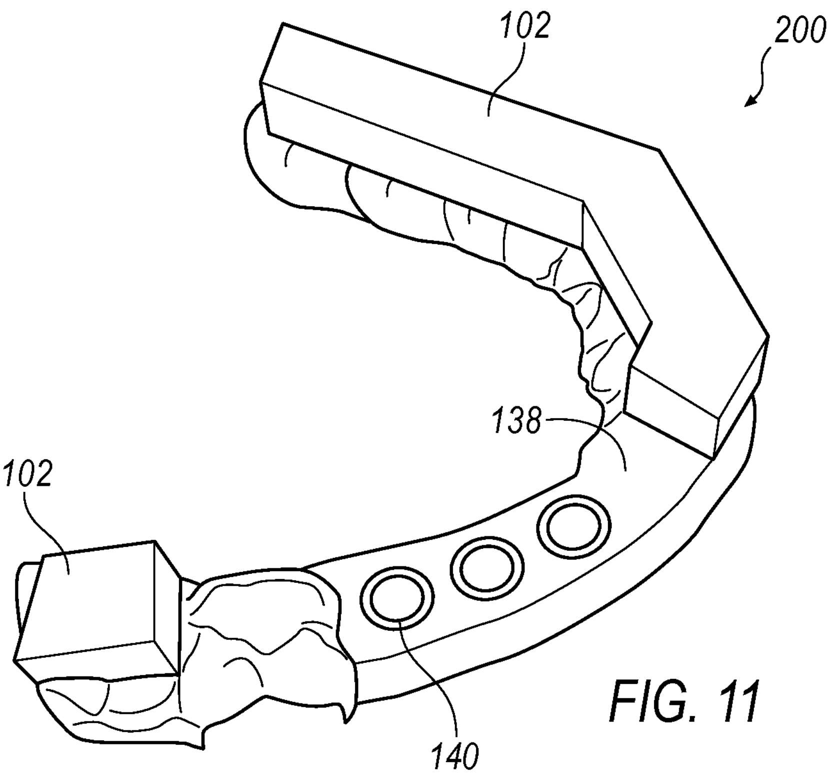

FIG. 11

CUSTOM LINKABLE IMAGING AND MULTIFUNCTIONAL TRAY

RELATED APPLICATIONS

This application claims priority under 35 U.S.C. §119(e) to U.S. Provisional Application No. 61/311,595 filed Mar. 8, 2010 and U.S. Provisional Application No. 61/370,950 filed Aug. 5, 2010. All of the foregoing applications are incorporated by reference herein in their entireties.

FIELD

The present disclosure relates to a dental device.

BACKGROUND

When preparing for a dental procedure, including dental implants, bone grafting and maxillofacial reconstruction, accurately determining an ideal location in the mouth for the procedure can be paramount to its success. For example, when inserting a dental implant, the patient's bone structure, the condition of the patient's bone density, and the presence of other oral structures in the mouth may effect where an implant is positioned. Therefore, a dentist and/or dental technician must be aware of the anatomical structures below the gum tissue, as well as, any structures located above the gum tissue.

Tomography scans have been used to capture images of structures located above and below the gum tissue. However, tomography scans including computerized tomography (CT) scan images, cone beam computerized tomography (CB CT) scan images, magnetic resonance imaging (MRI) scan images, and other 3D imaging devise are subject to image scattering when certain materials such as filings or crowns are present in a mouth. Thus, tomography scans may be unreliable, inaccurate and unusable as a proper diagnostic tool.

Surface scans including intra-oral scanners, optical image scanners, and laser image scanners have also been used to capture images of structures located in a mouth. However, surface scans may not accurately depict structures existing below the gum tissue.

Given scatter and other types of inaccuracies in the data, simply aligning an outline of oral structures in tomography scan data to an outline of the same structures in surface scan data may not accurately represent the location of oral structures within a mouth. Therefore, there is a need for a device that may be used to accurately align tomography scan data and surface scan data to provide a more accurate representation of a mouth. There is also a need for a system for using the device to more accurately align the tomography scan data set and the surface scan data.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an exemplary multifunctional tray

FIG. **2***a* is an exemplary tooth receiving cavity.

FIG. **2***b* is an exemplary tooth receiving cavity.

FIG. **3***a* is an exemplary tooth receiving cavity.

FIG. **3***b* is an exemplary tooth receiving cavity.

FIG. **4** is an exemplary multifunctional tray having a window.

FIG. **5** is a top view of an exemplary multifunctional tray.

FIG. **6** is an exemplary multifunctional tray having a plurality of markers.

FIG. **7** is an exemplary multifunctional tray having a single fiducial reference marker.

FIG. **8***a* is an exemplary system of using a multifunctional tray of the type illustrated in FIGS. **1** and **4**-**7**.

FIG. **8***b* is an exemplary system of using a multifunctional tray of the type illustrated in FIGS. **1** and **4**-**7**.

FIG. **9** is an exemplary multifunctional tray having an attachable diagnostic design.

FIG. **10** is an exemplary multifunctional tray.

FIG. **11** is an exemplary multifunctional tray.

DETAILED DESCRIPTION

Referring now to the discussion that follows and also to the drawings, illustrative approaches are shown in detail. Although the drawings represent some possible approaches, the drawings are not necessarily to scale and certain features may be exaggerated, removed, or partially sectioned to better illustrate and explain the present disclosure. Further, the descriptions set forth herein are not intended to be exhaustive or otherwise limit or restrict the claims to the precise forms and configurations shown in the drawings and disclosed in the following detailed description.

FIG. **1** illustrates an exemplary custom linkable multifunctional tray **100** that allows accurate combining and linking of data from different imagining devices. The multifunctional tray **100** may take many different forms and include multiple and/or alternate components. While an exemplary multifunctional tray **100** is shown in FIG. **1**, the exemplary components illustrated in the figure are not intended to be limiting. Indeed, additional or alternative components and/or implementations may be used. An exemplary method of manufacturing the multifunctional tray **100** and a system for using the multifunctional tray **100** to combine and link data are also described in more detail below.

Multifunctional tray **100** may include a frame **102** and at least one marker **104**. The tray **100** may also include a clasping portion **106**. However, some exemplary trays may be comprised of marker **104** and clasping portion **106**.

Clasping portion **106** may have at least one tooth receiving cavity **110** formed therein. However, as illustrated in FIG. **1**, clasping portion **106** may also have a plurality of teeth receiving cavities. The teeth receiving cavities **110** may be designed to extend along the entire dental arch of a patient when the tray **100** is inserted into a mouth. The teeth receiving cavities **110** may also be designed to extend partially along the dental arch of a patient when the tray **100** is inserted into a mouth. As illustrated in FIG. **1**, when tray **100** is inserted, the teeth receiving cavities **110** are designed to extend partially along opposing sides of a dental arch. However, other exemplary trays may include teeth receiving cavities **110** designed to extend partially along the front of the dental arch when the tray **100** is inserted. The number and location of the teeth receiving cavities **110** may be determined by the oral structures present in a mouth and/or the type of treatment needed. Although described as a tooth receiving cavity, the clasping portion **106** may be designed to contact, clasp, or otherwise engage various oral structures including, but not limited to, implants, prostheses, and gum tissue.

As illustrated in FIG. **2***a*, the tooth receiving cavity **110** may be designed to have limited occlusal surface contact with an oral structure **112**. That is, the tooth receiving cavity **110** may not engage the entire tooth or other oral structure **112**. For example, the tooth receiving cavity **110** may include at least one occlusal rest **114**. The occlusal rest **114** may extend inwardly from the tooth receiving cavity **110** and may contact the occlusal surface of the oral structure **112** at an occlusal contact point **116**. Although illustrated as substantially triangular in FIG. **2***a*, occlusal rest **114** may take on a variety of shapes. Indeed, the occlusal rest **114** may be designed and customized to fit the unique oral features of a patient. The occlusal rest **114** may also be formed integrally with the tooth receiving cavity **110**, the manufacture of which will be discussed in more detail below. In other exemplary embodiments, the tooth receiving cavity **110** may also be designed to have limited incisal surface contact or limited crest of the ridge surface contact with an oral structure **112**. That is, the tooth receiving cavity **110** may include at least one incisal rest **115** or, as illustrated in FIG. **4**, the tooth receiving cavity may have a combination of occlusal rests **114** and incisal rests **115**.

In addition to providing limited surface contact, the occlusal rest **114** and/or the incisal rest **115** may assist in stabilizing clasping portion **106** when tray **100** is inserted into a mouth. Referring back to FIG. **2***a*, the tooth receiving cavity **110** may also include one or more stabilizing rests **118**. Similar to the occlusal rest **114** and the incisal rest **115**, the stabilizing rest **118** may extend inwardly from the tooth receiving cavity **110** and contact an oral structure **112**. However, the stabilizing rest **118** may be designed to contact the occlusal surface, the incisal surface, or any other surface of an oral structure **112**. The stabilizing rest **118** may also take on a variety of shapes and may be customized to fit the unique oral features of a patient. The stabilizing rest **118** may also be formed integrally with the tooth receiving cavity **110**. Although FIG. **2***a* is illustrated as having one stabilizing rest **118**, a plurality of stabilizing rests **118** may be used when designing the clasping portion **106**.

The tooth receiving cavity **110** may also be designed to contact, clasp, or otherwise engage the undercut of an oral structure **112**. That is, the tooth receiving cavity **110** may include an undercut clasp **120** that allows the tray **100** to remain in position once the tray **100** is inserted into a mouth. The undercut clasp **120** may extend inwardly from the tooth receiving cavity **110** such that the undercut clasp **120** engages a lateral surface of the oral structure **112** at a lateral contact point **122**. As illustrated in FIG. **2***a*, a lateral contact point **122** may be formed between a plurality of undercut clasps **120** and the oral structure **112**. However, other configurations may be used.

For example, FIG. **2***b* illustrates lateral contact point **122** as a single contact point between the undercut clasp **120** and the oral structure **112**. However, FIG. **2***b* also illustrates an opposing portion **123** of the tooth receiving cavity **110** in reciprocating contact with the oral structure **112**. The reciprocating contact allows the clasping portion **106** to reciprocate back and forth along the surface of the tooth during installation and removal of the tray **100**. The reciprocating contact prevents an oral structure **112** from moving during installation and removal.

The undercut clasps **120** may be formed using a material flexible enough to allow clasping portion **106** to engage the teeth, gum tissue or other oral structures. The undercut clasps **120** may be formed integrally with the teeth receiving cavities, discussed in more detail below, or they may be formed separately. For example, the undercut clasps **120** may be snap-lock hinges, screws, pegs, or other suitable structures. Such structures may be used when a patient has an orthodontic appliance, such as braces. As illustrated in FIG. **3***a*, tooth receiving cavity **110** is configured to accept a screw, bolt, or other suitable structure. The screw **126** may be used to engage a surface of an orthodontic appliance **128** to create an undercut clasp **120**. However, as illustrated in **3***b*, the screw **126** or other suitable structure may also be used to engage a surface of an oral structure **112** to create an undercut clasp **120**.

The tooth receiving cavity **110** may also include a lateral band **124**. The lateral band **124** may also be designed to contact, clasp, or otherwise engage an oral structure **112**. Referring back to FIG. **1**, the lateral band **124** may extend inwardly from the clasping portion **106** and along the perimeter of the tooth receiving cavities **110**. As illustrated, when the tray is installed, the lateral band **124** creates a band of contact between the clasping portion **106** and the oral structure **112**. The lateral band **124** may be a continuous band or the lateral band **124** may be formed from multiple sections. The lateral band **124** may also be formed around a plurality of teeth or the undercut band **124** may be formed around a single tooth, an implant, a prosthesis, gum tissue, or any other suitable oral structures capable of supporting the tray **100**.

Although illustrated in FIG. **1** as engaging the undercut of each oral structure in contact with the clasping portion **106**, the lateral band **124** may be designed to meet the needs of a particular mouth. For example, portions of the lateral band **124** may engage the undercut of an oral structure **112** and some portions of the band may contact a lateral surface of the oral structure **112** in order to assist in stabilizing the tray **100** or to provide reciprocating contact with the oral structure **112**. Portions of the lateral band **124** may also be used to define a space between an oral structure **112** and a certain area or areas of the tooth receiving cavity **110** and portions of the band may not contact an oral structure at all. Accordingly, the lateral band **124** may be designed on different planes of the clasping portion **106** instead of just in one plane as illustrated in FIG. **1**. That is, a portion of the lateral band **124** may engage the undercut of one oral structure and contact an upper lateral surface of an adjacent oral structure to define a space between the oral structure **112** and the tooth receiving cavity **110**. Therefore, the lateral band **124** may be designed and customized to fit the unique oral features of a patient. The lateral band **124** may also be formed integrally with the tooth receiving cavity **110**, the manufacture of which will be discussed in more detail below.

The lateral band **124** may assist in stabilizing the clasping portion **106** by contacting the sub equatorial areas of an oral structure or a plurality of oral structures when tray **100** is inserted into a mouth. The lateral band **124** may also maintain the tray **100** in position once the tray **100** is inserted into a mouth.

The use of the occlusal rest **114**, the incisal rest **115**, the undercut clasp **120**, and/or the lateral band **124** allows the tray **100** to be placed tightly and securely onto a single tooth, multiple teeth and/or other oral structure. This eliminates the concern that the device may dislocate while being worn by the patient. This design also allows the device to fit securely onto an oral structure or structures with near perfect repeatability. The clasping portion **106** may also be designed to be placed tightly and securely onto gum tissue for use in edentulous or partially edentulous patients.

The clasping portion **106** may also have one or more windows **132** formed in the teeth receiving cavities **110** to determine whether the tray **100** is positioned correctly in a mouth. As illustrated in FIG. **4**, the window **132** may be formed in areas of the teeth receiving cavities **110** where an occlusal rest **114** and/or an incisal rest **115** is positioned. The window **132** allows a doctor and/or a technician to verify that the tray **100** is positioned accurately in the mouth by observing the position of the occlusal rest **114** and/or in the incisal rest **115** with respect to the occlusal surface or the incisal surface of a tooth or other oral structures. Although window **132** is illustrated as rectangular in shape, the window **132** may be formed as any suitable shape that allows a doctor and/or technician to view the position of the occlusal rest **114** and/or the incisal rest **115**.

Referring back to FIG. **1**, the frame **102** may be positioned adjacent to a top outer surface of the clasping portion **106**. As illustrated in FIG. **1**, the frame **102** may extend along a top outer surface of the clasping portion **106** opposite the teeth receiving cavities **110**. The frame **102** may extend along the entire top outer surface of the clasping portion **106** or the frame **102** may extend along a portion of the clasping portion **106**. The frame **102** may include a stabilizing bar **131**. In some cases, the frame **102** may have a stop **136**. The stop **136** may be used to prevent oral structure(s) of the opposing dental arch from contacting the tray **100** when the tray **100** is inserted in a mouth.

In another exemplary tray illustrated in FIG. **5**, a first portion of the frame **102** may extend along the top outer surface of the clasping portion **106** and a second portion may extend along an outer lateral surface of the clasping portion **106**. The frame **102** may also include a portion that extends outwardly from the dental arch. The portion of the frame **102** extending outwardly from the dental arch may not contact a surface of the clasping portion **106**. This portion of the frame **102** may take on any suitable configuration and may be used to ease insertion and removal of the tray **100**. The portion of the frame **102** extending outwardly from the dental arch may also be used to determine the position of the frame **102** in a tomography scan.

The frame **102** may be formed integrally with the clasping portion **106** or the frame **102** and the clasping portion **106** may be formed separately and assembled prior to taking a tomography scan of the tray. Although illustrated in FIGS. **1** and **5** as positioned adjacent to the clasping portion **106**, the frame **102** may also be partially embedded in the clasping portion **106**.

As discussed above, the multifunctional tray **100** may also include at least one marker. The frame **102** may be used to support the marker **104**. As illustrated in FIG. **6**, the marker **104** or plurality of markers may be disposed substantially within the frame **102**, partially disposed within the frame **102**, and/or disposed adjacent to the frame **102**, or any combination thereof. The marker **104** may be formed integrally with the frame or the marker **104** may be releasably engagable with the frame **102**. For example, the frame **102** may include a marker receptor **105** configured to receive a marker **104** or configured to be injected with a radio-opaque material to form a marker **104**.

Moreover, in another exemplary tray **100**, the marker **104** may be supported by or disposed in the clasping portion **106**. The marker **104** may be formed integrally with the clasping portion **106** or the marker **104** may be releasably engagable with the clasping portion **106**. For example, the clasping portion may include a marker receptor configured to receive a marker or configured to be injected with a radio-opaque material to form a marker.

Although illustrated as substantially spherical, the marker **104** may be designed as any suitable geometric shape or combination of geometric shapes. For example, the marker **104** may be substantially cuboidal or substantially cylindrical.

The marker **104** may be formed from a radio-opaque material, a non radio-opaque material, or a combination thereof. The radio-opaque material may be a thermoplastic, a ceramic, or any other suitable material, or any suitable combination of materials capable of inhibiting electromagnetic radiation. This allows the marker **104** to be viewable during CT scans, CB CT scans, CB VT scans, MRI scans, and other types of three-dimensional surface scanning. The marker may also be viewable in surface scans.

The marker **104** may also be a radiodensity comparative reference marker. Radiodensity comparative reference markers may be formed using various chemical compositions. This allows the marker **104** to have a different radiodensity based on the chemical composition that is selected. One benefit of using radiodensity comparative reference markers is that the accuracy of the tomography scan data may be evaluated using such markers. For example, CTs or MRIs create a series of two dimensional pictures that may vary in accuracy depending on whether or not the machine is properly calibrated. When reconstructing tomography scan data into three dimensional images, often done with volumization software, a threshold value of grey scale radiodensity may be quantified using a Hounsfield Unit (HU). However, the software threshold value may not be consistent with the threshold value indicated in the scan data file, since each read out of the scan data may be affected by one or more factors such as the calibration of the scanner, the method of image acquisition, the computer software being used, or image scatter. However, the use of a radiodensity comparative reference marker may provide a "built-in" standard. That is, the operator may use a radiodensity comparative reference marker with a known density as a reference to tune the threshold setting of the software for volumization of the data file. This standard may give users a tool to evaluate the tomography data file and to create more accurate bone models.

Another benefit of using radiodensity comparative reference markers is that the reference marker may be used to mimic various degrees of bone density during a tomography scan. Therefore, a radiodensity comparative reference marker with a known density may be used as a reference to tune the threshold settings of the volumization software. This may provide a model with a more accurate representation of a patient's bone density. The condition of patent's bone density can affect the success of a dental treatment, especially with respect to the placement of a dental implant.

Another exemplary marker **104** that may be used with the multifunctional tray **100** is a negative reference marker. By designing a cavity or other similar structure of a certain size and geometric shape into the frame **102** or adjacent to clasping portion **106**, a negative linkable marker can be created. This cavity, which is substantially devoid of material, will appear as a geometric shaped black space in the tomography scan data of a patient when the threshold density is set at the same radiodensity density level as the frame **102**. This density level may be the same as the density level of skin. The use of a negative reference marker may increase the accuracy of the tomography scan data because the empty space will offer the clearest image of the marker outline without distortion.

As another example, the space defined between the clasping portion **106** and the oral structure **112** may be used as a negative reference marker. The use of the occlusal rest **114**, the incisal rest **115** and/or the undercut clasp **120** may create a space between the clasping portion **106** and the oral structure **112**. As discussed above, the image of this geometric black space may be used to verify the accuracy of the tomography scan data. The image may also be used to determine whether the tray is positioned correctly in a mouth during the tomography scan.

Although FIG. **6** illustrates a tray **100** having a plurality of markers **104**, a single fiducial reference marker may be used to accurately combine and link data from different imagining devices. As discussed above, the single marker may be disposed substantially within the frame **102**, partially disposed within the frame **102**, and/or disposed adjacent to the frame **102**.

In one exemplary tray **100**, as illustrated in FIG. **7**, the tray **100** has a clasping portion **106**, a frame **102** and single fiducial reference marker **204**. In FIG. **7**, the frame **102** defines the single fiducial reference marker **204**. As illustrated, the single fiducial reference marker **204** may extend along the entire dental arch of a patient. However, the single fiducial reference marker **204** may also be designed to extend partially along the dental arch.

As discussed above, the single fiducial reference marker **204** defined by the frame **102** may be formed from a radio-opaque material, a non radio-opaque material, or a combination thereof. The fiducial reference marker **204** may also be a negative reference marker. Thus, the marker **204** may be viewable in a tomography scan and may be used to combine and link data from different imaging devices, discussed in more detail below. Although not illustrated, the tray **100** in FIG. **7** may also include at least one radiodensity comparative reference marker with a known density that may be used as a reference to tune the threshold settings of the volumization software.

The exemplary multifunctional trays discussed above may be designed using various methods. For example, the multifunctional tray **100** may be designed using a digital dental model of a mouth. The digital dental model may be obtained using a surface scanning device, such as an intra oral scanner, to scan the oral structures present in the mouth. The surface scan data may then be save as a CAD compatible file and opened using a modeling system or other suitable system for appropriate analysis and manipulation. Such systems may include hardware, software or a combination of hardware and software. Surface scan data may also be obtained from surface scanning a dental model of the mouth.

Once the digital dental model has been created from the surface scan data, the frame **102** and the clasping portion **106** may be digitally designed. The clasping portion **106** may be digitally designed on the digital dental model using the hardware and/or software system discussed above. Using the digital dental model, the clasping portion **106** may be designed to fit the unique contours of a mouth, including the contours of individual oral structures. For example, referring back to FIG. **2***a*, the occlusal rest **114** extending inwardly from tooth receiving cavity **110** may be designed to fit the contours of the occlusal surface of a particular tooth. Similarly, the undercut clasp **120** extending inwardly from a tooth receiving cavity **110** may be designed to fit the contours of the undercut of a particular tooth. Thus, the digital dental model allows a dentist and/or a dental technician to customize a digital tray for each patient based on the oral structures present and/or type of treatment needed.

The frame **102** may also be digitally designed on the digital model using the hardware and/or software system discussed above. The frame **102** may be digitally designed as a single fiducial reference marker **204**, as illustrated in FIG. **7** and discussed above. The frame **102** may also be digitally designed to include a single fiducial reference marker and/or plurality of markers **104**.

Optionally, as illustrated in FIG. **9**, diagnostic teeth **134** and/or components necessary to convert the tray into a diagnostic appliance may be digitally designed. The diagnostic teeth **134** and/or other components may be designed integrally with the digital tray. However the diagnostic teeth **134** and/or the other components may also be designed as separate structures configured to be attachable and detachable to the tray.

Once the components of the digital tray have been designed on the digital model, the tray **100** may be manufactured. The tray may be manufactured using a 3D printer, a stereolithography device, a CNC machine or any other suitable CAM device. The tray **100** may be manufactured from any suitable FDA approved material including, but not limited to, photopolymer, resin, or other radio-transparent/radio-translucent materials. Radio-translucent metals such as Titanium may also be used or added to the tray. If desired, portions of the tray **100** may also be formed by hand. For example, marker **104** may be pre-made and placed into the receptor cites **105** after the tray has been manufactured.

The digital tray design may be saved in a data file with the digital dental model. Thus, the data file includes information related to the position and orientation of the digital tray in relation to the oral structures of a mouth, and may be used as a reference. Use of the data file as a reference is discussed in more detail below.

FIG. **8***a* illustrates an exemplary approach for using the tray **100** and the associated digital tray, discussed above, to select a surgical site or to perform other dental procedures, including determining locations for dental implants. As shown in block **300***a*, the tray **100** may be positioned in a mouth. Once positioned, a doctor may verify that the fit of the tray based on the position of the tray in the mouth and/or by observing the position of an occlusal rest **114** and/or an incisal rest **115** through a window **132**, if the tray is configured with such components.

As shown in block **302***a*, after the tray **100** is positioned, a tomography scan of the mouth may be performed. The tomography scan may be performed using a CT, a CB CT, a CB VT, an MRI, or any other suitable imaging device. Multiple tomography devices may also be used to create different types of tomography images. The data collected from the tomography scan or scans, including the orientation and positioning of the tray, may be used to create a tomography scan data set. In some instances, a surface scan of the mouth may also be performed to create a surface scan data set.

After the tomography scan has been performed, the tomography scan data set and the surface scan data set used to create the digital tray may be aligned to create a combined master data file, as shown in block **304***a*. To create the combined master data file the tomography scan data may first be analyzed using tomography data volumalizing and converting software. The volumalizing software is used to reconstruct two dimensional pictures into three dimensional images. Using the software, the placement of the tray **100** in a mouth may be verified. That is, the tomography scan data set may be used to measure the position of the tray **100** relative to an oral structure. This measurement may then be compared to the same measurement done using the surface scan data set used to digitally create the tray. Once the tomography scan data has been volumalized and its accuracy verified, the data may be converted to CAD (computer aided design) compatible data and exported to a modeling system or any other suitable system for appropriate analysis and manipulation.

In some situations it may be beneficial to segment different portions of the tomography scan data to create digital models that represent individual sections of a mouth. Indeed, the tomography scan data set may be segmented into portions representing the jaw bone, teeth, roots, nerves, etc. If the tray **100** has at least one radiodensity reference marker, as discussed above, the reference marker may be used to create models of individual sections of an oral structure. That is, different oral structures may have different densities. Thus, by using the reference marker to tune the threshold setting of the software, different oral structure may be viewable in better detail.

Once the tomography scan data has been collected and saved, the surface scan data set including the surface scan data of the mouth and the digital tray, may be opened using the same modeling software. In one exemplary approach, the tomography scan data set may be aligned with or superimposed over the surface scan data set using the digital tray design. As discussed above, the tomography scan data set may be aligned with the surface scan data set using the digital tray having a single fiducial reference marker **204**, a single marker or a plurality of markers **104** as a position reference. Use of the digital tray design also allows for additional design options for the dental tray and the marker. For example, the tray **100** may be designed with a marker entirely or partially enclosed in the frame **102** and/or the clasping portion **106**. Although an entirely or partially enclosed marker may not be fully detectable in a tomography scan data set and/or a surface scan data set, the marker would be visible when the data sets were aligned using the digital tray design.

When aligning the data sets to create a master data file, the tomography scan data set and the surface scan data set do not have to have a common plane. Instead, each image can be oriented according to the digital design of the device. By aligning the tomography scan data set and the surface scan data set, portions of the tomography scan data distorted by scatter or other inaccuracies may be replaced with more accurate surface scan data.

Although one exemplary approach for aligning the scan data sets is provided, other approaches for aligning the data may be used. For example, multiple data sets may be aligned to create the master data file. Multiple data sets may exist if manual adjustment of the tray **100** was needed to readjust the fit of the tray inside a mouth. In such cases, a doctor or technician may need to surface scan the adjusted tray while the tray is inserted in the mouth or positioned on a dental model. Accordingly, the additional set of surface scan data may need to be aligned to the original surface scan data set and the tomography scan data set in order to create the combined master file. Multiple data sets may also exist if a plurality of tomography scan devices were used to capture the oral structures of a mouth.

The digital tray design may also be used to verify the scaling and sizing of the data contained within the tomography scan data. Verifying the scaling and sizing of the data is important when precision treatment is necessary, such as during implant placement and other oral treatments.

In another exemplary approach, the scan data sets may also be aligned without the digital tray if the tray is designed so that the marker is viewable in the surface scan data. For example, as illustrated in blocks **300***b* and **302***b* of FIG. **8***b*, a tomography scan of the mouth, including the inserted tray **100**, may be performed. The tomography scan may be performed using a CT, a CB CT, a CB VT, an MRI, or any other suitable imaging device.

A surface scan of the mouth including the tray **100** may also be performed in order to create a surface scan data set, as illustrated in block **304***b*. The surface scan data may be collected by performing an intra-oral surface scan of the mouth. The surface scan data may also be collected by performing an optical image scan, a laser image scan or any other type of surface scan of a dental model that is created from a dental impression of a mouth, which includes the orientation and positioning of the tray as well as any other oral structures present on the outer surface of the gum tissue and inside the mouth.

After the tomography scan and surface scan have been performed, the tomography scan data set and the surface scan data set may be aligned to create a combined master data file, as illustrated in block **306***b*. As discussed in more detail above, to create the combined master data file the tomography scan data may first be analyzed using tomography data volumalizing and converting software. Once the tomography scan data has been volumalized and its accuracy verified, the data may be converted to CAD compatible data and exported to a modeling system or any other suitable system for appropriate analysis and manipulation. Such system may include hardware, software or a combination of software and hardware.

When the tomography scan data set has been translated into a file format that corresponds with the surface scan data set, the tomography scan data and the surface scan data may be linked to create a master data file. That is, the presence of the tray **100** including at least one marker in the tomography scan data set and a corresponding tray and marker in the surface scan data set provides a temporary positioning reference location in each data set. These corresponding temporary positioning reference locations enable accurate linking of the data sets because the reference locations present in both scan data sets can be aligned. Thus, the master data file will contain an accurate representation of an entire mouth—the tomography scan data provides imaging of the structures underneath the gum tissue including bone density information and the surface scan data provides imaging of the surface structures of a mouth including oral structures. Moreover, portions of the tomography scan data distorted by scatter or other inaccuracies may be replaced with more accurate surface scan data. Thus, the master data file may be used for evaluation of potential locations for dental procedures or to create a digital or physical diagnostic model.

The linked data from the tomography scan and the surface scan may also be used to verify the scaling and sizing of the data contained within the tomography scan data set and the surface scan data set. Verifying the scaling and sizing of the data is important when precise implant placement is paramount due to the type of implant needed. One way to verify the scaling and sizing of the scanning images is to compare the known size and shape measurements of the tray **100** to the size and shape measurements of digital tray as it appears in the scanning images.

After the data sets have been aligned to create a combined master data file, using the digital design of the tray and/or a marker, the master data file can then be used for evaluation or to create a digital or physical diagnostic model that contains accurate bone structure and tissue representations. Diagnostic designs including teeth, veneers, tissue and implant components may also be added to the master data file.

As illustrated in FIG. **9**, the tray **100** may be designed to include attachable and detachable diagnostic teeth **134** or diagnostic teeth that are formed integrally with the tray. The diagnostic teeth **134** may be formed of a radio opaque or non-radio opaque material or a combination thereof. The diagnostic teeth **134** may also be designed as solid or hollow structures, or the diagnostic teeth may be designed to have a veneered surface of a part of a tooth structure. The teeth **134** may be attached to the tray **100** using any suitable method including snapping, sliding, and/or screwing the diagnostic teeth onto the tray in order to determine the aesthetics and the functions of potential implant locations. The diagnostic teeth **134** may also be attached to the tray during tomography scanning so that the teeth are visible in the scan data. The diagnostic teeth **134** may also be designed to be detachable from the tray and attachable to a physical diagnostic model created from the master data file.

In another exemplary embodiment, illustrated in FIG. **10**, the tray **200** may include a clasping portion **106** and a frame **102**. The tray **200** may be designed and configured to be used as the frame for a surgical drill guide, a transfer jig, or other dental appliance. Similar to FIG. **9**, the tray **200** may be designed to include integrated, or wholly or partially attachable and detachable diagnostic structures **134**. The diagnostic structures may be, but are not limited to, mouth to model or model to model transfer components and diagnostic teeth.

The diagnostic structures **134** may be attached to the tray **200** using any suitable method including snapping, sliding, and/or screwing the diagnostic structure onto the tray in order to determine the aesthetics and function of potential implant locations. The diagnostic structure may also be adhered to the tray **100** using a light curable composite or any other suitable adhesive material. The diagnostic structures **134** may also include apertures formed therein such that the tray **200** may be used as a surgical guide, for dental implants and other oral procedures. That is, the tray **200** may be used during a dental procedure to guide a dentist when making an incision, drilling a pilot whole, or inserting an implant.

When the detachable diagnostic structure **134** is removed from the tray **200**, the frame may include a tissue contour veneer **136**, as illustrated in FIG. **10**. The tissue contour veneer **136** represents the top surface of a patient's gum tissue, including the unique contours of the tissue. Thus, the tissue contour veneer **136** may be used to determine where the bottom of an implant may be positioned to provide proper and aesthetically pleasing contouring between the gum tissue and the implant.

In another exemplary embodiment, illustrated in FIG. **11**, the tray **200** may include a clasping portion **106**, a frame **102**, and an extension member **138**. The extension member **138** may extend between individual sections of clasping portion **106** or the extension member **138** may be designed as part of clasping portion **106**. The extension member **138** may include one or a plurality of bushings **140** extending there through. Although, illustrated as tubular bushings, the bushings **140** may take on any suitable shape or structure, including open-face bushings. The bushings **140** may be formed integrally with the extension member **138** or they may be attached to the extension member in any suitable manner. For example, the bushings **140** may be attached to the extension member **138** using a light cured composite material. The bushings **140** may be used to attach diagnostic structures to the tray **200** or to configure the tray **200** into a surgical guide, and implant placement guide, and/or a transfer jig.

The clasping portion **106** of the tray **200** provides an advantage to a dentist when the tray **200** is being used as a surgical guide or transfer jig. That is, the clasping portion **106** allows the tray to be positioned securely to the contours of a mouth. This allows the tray to be inserted, removed and reinserted into the mouth in the same position repeatedly. Thus, when using the tray as a surgical guide, the dentist may rely on the tray to indicate the precise location of an implant site. Moreover, the clasping portion eliminates the need for the tray to be held in place by a dentist, a dental assistant, or a technician during use.

The trays **200** illustrated in FIGS. **10** and **11** may be formed by digitally or manually altering an imaging tray or the trays **200** may be designed and manufactured independently. The clasping portion **106** of the tray **100** may also be utilized in other types of dental appliances including, but not limited to, bite guards, bite splints, night guards, anti-snoring appliance, face bow transfer jigs, bleaching trays, impression trays, orthodontic retainers, orthodontic appliances for bracket placement, orthognathic stents, loose teeth stabilizing appliances, and sleep apnea appliances.

Although the method steps are listed in an exemplary order, the steps may be performed in differing orders. Furthermore, one or more steps may be eliminated and other exemplary steps may be added between the initial stage and the final stage.

The present disclosure has been particularly shown and described with reference to the foregoing illustrations, which are merely illustrative of the best modes for carrying out the disclosure. It should be understood by those skilled in the art that various alternatives to the illustrations of the disclosure described herein may be employed in practicing the disclosure without departing from the spirit and scope of the disclosure as defined in the following claims. It is intended that the following claims define the scope of the disclosure and that the method and apparatus within the scope of these claims and their equivalents be covered thereby. This description of the disclosure should be understood to include all novel and non-obvious combinations of elements described herein, and claims may be presented in this or a later application to any novel and non-obvious combination of elements. Moreover, the foregoing illustrations are illustrative, and no single feature or element is essential to all possible combinations that may be claimed in this or later applications.

All terms used in the claims are intended to be given their broadest reasonable constructions and their ordinary meanings as understood by those knowledgeable in the technologies described herein unless and explicit indication to the contrary is made herein. In particular, use of the singular articles such as "a," "the," "said," etc. should not be read to recite one or more of the indicated elements unless a claim recites an explicit limitation to the contrary.

What is claimed is:

1. A patient specific dental tray having a dental frame defining a receiving cavity configured to receive at least one oral structure that is positioned within the receiving cavity, the received oral structure having an outer surface with an upper surface and a lateral surface comprising:

a dental frame including:

- a top wall,
- at least one lateral wall extending from the top wall,
- at least one rest extending away from the top wall into the receiving cavity, and
- at least one lateral contact extending away from the lateral wall into the receiving cavity; and

the receiving cavity defining a pre-measured open space between the outer surface of the oral structure to be received and the dental frame such that the upper surface is spaced from the top wall with the at least one rest selectively engaging the upper surface and the lateral wall is spaced away from the lateral surface with the at least one lateral contact engaging the lateral surface, the dental tray configured such that a majority of the outer surface of the oral structure to be received is positioned within the dental frame of the dental tray is free from contact with any element of the dental tray, further including a marker configured to be a positioning reference usable for aligning multiple data files from different data sources, the marker comprising a tube extending along at least a majority of the dental frame, but not interfering with the receiving cavity, the tube having an interior air space defined along its axial extent and defining a negative marker, the negative marker fixing in three dimensions a location of the dental tray.

2. The dental tray of claim **1**, wherein the marker is at least one of disposed substantially within the dental tray, disposed partially within the dental tray, and disposed adjacent to the top wall.

3. The dental tray of claim **1**, wherein the receiving cavity defines a negative fiducial marker.

4. The dental tray of claim **1**, wherein the tube is unitary and cylindrical.

5. The dental tray of claim **2**, wherein the tube abuts the top wall.

6. The dental tray of claim **1**, the tube having at least one transition such that a first region of the tube has a first axial extent and a second region of the tube has a second axial extent dissimilar from the first axial extent, the at least one transition defined between the first region and the second region.

7. The dental tray of claim **1**, wherein the marker is one of integral with the dental frame and releasably engagable with the dental frame, and engaging the top wall.

8. The dental tray of claim **1**, further including a radiodensity comparative reference marker as a reference when volumalizing a tomography data file.

9. The dental tray of claim **1**, further comprising at least one diagnostic design wherein the diagnostic design is one of releasably engagable with the frame and formed integrally with the frame.

10. The dental tray of claim **1**, wherein the dental tray is configured to be used as one of a surgical guide and a transfer jig.

11. The dental tray of claim **1**, wherein the dental tray is configured to extend about at least a portion of a dental arch, a plurality of occlusal rests disposed along the dental arch.

12. The dental tray of claim **1**, wherein the dental tray is configured to extend about at least a portion of a dental arch, a plurality of lateral contacts disposed along the dental arch.

13. The dental tray of claim **1**, wherein there are two lateral walls, each lateral wall extending from opposing edges of the top wall.

14. The dental tray of claim **13**, wherein the first lateral wall and the second lateral wall intersect.

15. The dental tray of claim **14**, wherein the intersect is at a distal end of the oral structure.

16. The dental tray of claim **1**, wherein the at least one lateral wall includes a free end, the at least one lateral contact extending away from the free end into the receiving cavity.

17. The dental tray of claim **1**, wherein at least one stabilizing rest extends from one of the at least one lateral wall and the at least one top wall.

18. The dental tray of claim **1**, wherein the open space consists essentially of air.

19. A patient specific dental tray having a dental frame defining a receiving cavity configured to receive at least one oral structure that is positioned within the receiving cavity, the received oral structure having an outer surface with an upper surface and a lateral surface comprising:

a dental frame including:

a top wall,

at least one lateral wall extending from the top wall,

at least one rest extending away from the top wall into the receiving cavity, and

at least one lateral contact extending away from the lateral wall into the receiving cavity; and

the receiving cavity defining a pre-measured open space between the outer surface of the oral structure to be received and the dental frame such that the upper surface is spaced from the top wall with the at least one rest selectively engaging the upper surface and the lateral wall is spaced away from the lateral surface with the at least one lateral contact engaging the lateral surface, the dental tray configured such that a majority of the outer surface of the oral structure to be received positioned within the dental frame of the dental tray is free from contact with any element of the dental tray

a marker configured to be a positioning reference usable for aligning multiple data files from different data sources, and wherein the marker is at least one of disposed substantially within the dental tray, disposed partially within the dental tray, and disposed adjacent to the top wall;

the dental tray extending about at least a portion of a dental arch, a plurality of the rests and the lateral contacts disposed at different positions along the dental arch; and

wherein there are two lateral walls, each lateral wall extending from opposing edges of the top wall, the first lateral wall and the second lateral wall intersecting at a distal end of the oral structure, the marker comprising a tube extending along at least a majority of the dental frame, but not interfering with the receiving cavity, the tube having an interior air space defined along its axial extent and defining a negative marker, the negative marker fixing in three dimensions a location of the dental tray, and wherein the tube is unitary and cylindrical, and abuts the top wall.

20. The dental tray of claim **19**, the tube having at least one transition such that a first region of the tube has a first axial extent and a second region of the tube has a second axial extent dissimilar from the first axial extent, the at least one transition defined between the first region and the second region.

21. A dental tray comprising:

an arcuate contiguous frame configured to extend along a dental arch between two distal ends and defining a receiving cavity configured to receive at least one oral structure having two opposing outer surfaces and an upper surface disposed therebetween, wherein the frame includes

opposing lateral bands,

a top wall defined therebetween,

a rest extending away from the top wall into the receiving cavity,

a lateral contact extending away from each of the lateral bands into the receiving cavity;

the receiving cavity defining a pre-measured open space between the outer surfaces of the received oral structure and the dental frame such that the upper surface is spaced from the top wall with only the at least one rest selectively engaging the upper surface and the lateral bands are spaced away from the lateral surface with only the lateral contacts selectively engaging the outer surfaces, the dental tray configured such that a majority of the outer surface of the received oral structure positioned within the dental frame of the dental tray is free from contact with any element of the dental tray, the marker comprising a tube extending along at least a majority of the dental frame, but not interfering with the receiving cavity, the tube having an interior air space defined along its axial extent and defining a negative marker, the negative marker fixing in three dimensions a location of the dental tray, and wherein the tube is unitary and cylindrical, and abuts the top wall.

22. The dental tray of claim **21**, wherein the lateral bands are each contiguous.

23. The dental tray of claim **21**, wherein the lateral bands are each selectively interrupted along the dental arch.

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